

**AMENDMENT TO THE DRAWINGS**

Kindly amend the drawings, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents as follows:

Kindly replace the previously filed drawings for Figures 1-19 with the enclosed formal drawings for Figures 1-19.

**REMARKS**

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

**1. Status Of the Specification**

Changes to the specification are intended to delete redundant priority information added by preliminary amendments. No new matter has been added by this amendment.

**2. Status Of Claims And Formal Matters**

Claims 1-23 are under consideration in this application. Claims 1-3, 5-9, 11, 15 and 19-22 have been amended and claims 4 and 10 has been canceled. No new matter has been added by this amendment.

Support for the recitation of sensitising the red blood cell by exposing it to an electric field is found on page 9, lines 10-15 of the specification as originally filed. Support for the recitation of sensitising and loading the red blood cell with an agent *in vitro* or *ex-vivo* is found on page 12, lines 6-17 of the specification. Support for the recitation of an electric field applied as an electric pulse is found on page 10, lines 19-21 of the specification. Support for the recitation of introducing the red blood cell to the target site in a vertebrate by transfusion or infusion is found on page 18, lines 5-14 of the specification.

The Examiner is thanked for indicating that all claims are free of the prior art of record. Claims 1-3, 5-9, 11, 15 and 19-22 have been amended without prejudice, without admission, and without surrender of subject matter, and without any intention of creating any estoppel as to equivalents to recite the base claim and intervening claims.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

**3. Status Of the Drawings**

Formal drawings are submitted to replace the previously submitted informal drawings. No new matter has been added by this amendment.

**4. The Objections to the Claims Are Overcome**

Claims 2 and 19 were objected to because they are ungrammatical. Claims 2 and 19 have been clarified to correct the grammatical errors, thereby obviating the objection.

Claims 22 and 23 were objected to as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. Claim 22 has been clarified to depend from independent claims 1, 8 or 15, thereby obviating the objection. Since claim 23 depends from claim 22, the objection to claim 23 is also obviated.

It is believed that the objections have been overcome. Reconsideration and withdrawal are requested.

**5. The Rejections Under 35 U.S.C. § 112, Second Paragraph, Are Overcome**

Claims 3, 6, 7 and 9-21 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 6 and 12 are allegedly indefinite because it is unclear what is the distinction between a “method” and a “use”. As suggested by the Examiner, claims 3 and 6 have been clarified to delete of recitations of “of use”, thereby obviating the rejection.

Claims 6, 7, 9-12 and 19 are allegedly indefinite because they recite “the sensitisation of the red blood cell” without proper antecedent basis. Claims 1, 8 and 15 have been clarified to replace the recitation of electrosensitising the red blood cell with sensitisation of the red blood by exposing it to an electric field. Therefore, proper antecedent basis exists for the sensitisation of the red blood cell in claims 6, 7, 9-12 and 19, thereby obviating the rejection.

Claims 8, 13, 14 and 18-21 are allegedly indefinite because they recite “the sensitised red blood cell” without proper antecedent basis. Claims 1, 8 and 15 have been clarified to replace the recitation of electrosensitising the red blood cell with sensitisation of the red blood by

exposing it to an electric field. Therefore, proper antecedent basis exists for the sensitised red blood cell in claims 8, 13, 14 and 18-21, thereby obviating the rejection.

Claim 11 is allegedly indefinite because it recites “the electric pulse” without antecedent basis. Claim 11 has been clarified to recite the electric field (of claim 8) is applied as an electric pulse, thereby obviating the rejection.

Claims 15-21 are allegedly indefinite because the claims recite no step in which delivery to a target site is achieved. Claim 15 has been clarified to recite that the red blood cell is introduced to the target site in a vertebrate by transfusion or infusion, thereby obviating the rejection. Since claims 16-21 depend from claim 15, the limitations of claim 15 are incorporated into claims 16-21, thereby obviating the rejection to claims 16-21.

Claims 1-21 are allegedly indefinite because it is unclear what are the metes and bounds of “electrosensitising”. As suggested by the Examiner, claims 1, 8 and 15 have been clarified to recite “sensitising the red blood cell by exposing it to an electric field to destabilise its membranes”, thereby obviating the rejection. Claims 2 and 9 has been clarified to recite “sensitizing” or “sensitisation” for proper antecedent basis. Claim 10 has been canceled. Since the remaining claims depend from claims 1, 8 and 15, the limitations of claims 1, 8 and 15 are incorporated into the remaining claims, thereby obviating the rejection.

It is believed that the rejections under 35 U.S.C. § 112, second paragraph, have been overcome. Reconsideration and withdrawal are requested.

## 6. The Rejections Under 35 U.S.C. § 112, First Paragraph, Are Overcome

Claims 1-21 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for methods of selectively disrupting with ultrasound an electrosensitised red blood cell which have not been loaded with an agent, or for methods requiring loading of agents into red blood cell *in vivo*, or for methods requiring loading of agents into red blood cells by viral infection.

Claims 1-3 and 12 are rejected as allegedly lacking enablement for methods of selectively disrupting with ultrasound an electrosensitised red blood cell which have not been loaded with an agent. As suggested by the Examiner, claim 1 has been clarified to incorporate the limitations of claim 4, thereby obviating the rejection to claim 1. Since claims 2, 3 and 12 depend from claim

1, the limitations of claim 1 are incorporated into claims 2, 3 and 12, thereby obviating the rejection to claims 2, 3 and 12.

Claims 1-21 are rejected as allegedly lacking enablement for methods requiring loading of agents into red blood cell *in vivo*. Although the Applicants do not agree with the Examiner, in the interest of expediting prosecution, claims 1, 8 and 15 have been clarified to recite that a red blood cell is loaded with an agent *in vitro* or *ex-vivo*, thereby obviating the rejection. Since the remaining claims depend from claims 1, 8 or 15, the limitations of claims 1, 8 or 15 are incorporated into the remaining claims, thereby obviating the rejection.

Claim 21 is rejected as allegedly lacking enablement for methods requiring loading of agents into red blood cells by viral infection. Although the Applicants do not agree with the Examiner, in the interest of expediting prosecution, claim 21 has been clarified to delete the recitation of viral infection, thereby obviating the rejection.

It is believed that the rejections under 35 U.S.C. § 112, first paragraph, have been overcome. Reconsideration and withdrawal are requested.

## **7. The Double Patenting Rejections Are Overcome**

Claims 1-21 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 4, 14-19, 36-40, 43 and 45-57 of co-pending U.S. Application No. 09/748,789.

The issue of whether there is indeed double patenting is contingent upon whether new claims herewith are indeed considered and entered; and, if so, whether the Examiner believes there is overlap with claims ultimately allowed in the co-pending application. If upon agreement as to allowable subject matter it is believed that there is still a double patenting issue, then, at that time, if indeed necessary, a Terminal Disclaimer as to co-pending U.S. Application No. 09/748,789 will be filed.

Accordingly, reconsideration and withdrawal of the double patenting rejection, or at least holding it in abeyance until agreement is reached as to allowable subject matter, is respectfully requested.

**REQUEST FOR INTERVIEW**

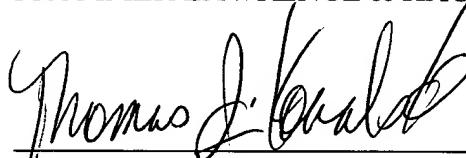
If any issue remains as an impediment to allowance, a further interview with the Examiner and SPE are respectfully requested; and, the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,  
FROMMER LAWRENCE & HAUG LLP

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